

**UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ALABAMA
NORTHEASTERN DIVISION**

EDWIN R. BANKS

Plaintiff,

v.

**ALEX M. AZAR, in his official
capacity as Secretary of the U.S.
Department of Health and Human
Services,**

Defendants.

Case No.: 5:20-cv-0565-LCB

MEMORANDUM OPINION AND ORDER

This case is before the Court on remand from the Eleventh Circuit. (Doc. 58). On March 30, 2021, this Court denied Banks's motion for summary judgment and granted the Secretary's motion for summary judgment. (Doc. 52). On appeal, the Secretary argued for the first time that Banks lacked Article III standing. The Eleventh Circuit vacated this Court's ruling and remanded the case for additional jurisdictional factfinding and a ruling on Article III standing in the first instance. *See Banks v. Sec'y of Health & Hum. Servs.*, No. 21-11454, 2021 WL 3138562, at *1 (11th Cir. July 26, 2021). The Eleventh Circuit directed this Court to consider supplemental evidence submitted by the parties as appropriate. *Id.*

Shortly after receiving the Eleventh Circuit's mandate, this Court held a telephone conference with the parties and ultimately allowed them to submit briefs

on the issue of Article III standing. Based on Banks's assertion that limited discovery would be needed on the standing issue, the Court also allowed Banks to file a brief regarding his discovery request. Once all issues were fully briefed, the Court held oral argument regarding both standing and discovery. The Court found oral argument appropriate on both issues because they appeared to be inextricably intertwined. The Court also noted that it might be inclined to conduct further arguments if it allowed Banks to conduct discovery. However, after considering the briefs, the parties' arguments, the evidence submitted, and two judicially noticed administrative opinions, the Court finds that Banks lacks Article III standing. As discussed below, the Court finds that the requested discovery would not change its determination and therefore will deny Banks's motion for discovery.

I. Factual Background

Banks is a retired Medicare beneficiary. (Doc. 31–1 at 22). In September of 2009, he was diagnosed with a type of brain cancer known as glioblastoma multiforme (GBM). GBM tumors are usually highly aggressive with a survival period of approximately ten months after initial presentation. *Id.* Banks was “prescribed chemotherapy, radiation and surgery to treat his [GBM].” *Id.* Banks learned in September of 2013 that, despite treatment efforts, his cancer had progressed. *Id.* Because of the cancer's progression, Banks's physicians prescribed the use of a medical device called Optune in December of 2013. *Id.* Optune is a

type of medical device that provides tumor treatment field therapy, or TTFT. TTFT works by sending alternating electric fields—or tumor treating fields—into the brain. (Doc. 31–1 at 22). This treatment slows or stops cancer cell growth. *Id.* The Optune device is expensive. It requires frequent and substantial servicing and is billed as a monthly rental. *Id.* at 23. According to Banks, the total cost for using Optune is approximately \$20,000 per month.

Banks submitted these charges to Medicare. As noted in this Court’s order on summary judgment, Banks received conflicting decisions from Medicare as to whether TTFT was covered. Wading through the administrative appeals process, which will be discussed in more detail below, Banks eventually presented his claims to an ALJ. One of the ALJ’s approved the use of TTFT for the month of February 2018 and the months of May 2018 through January 2019. However, a different ALJ found that TTFT was not covered for the months of January, March, and April of 2018. The underlying complaint in this case challenged that denial on grounds of collateral estoppel. This Court found that collateral estoppel did not apply to Medicare proceedings like those at issue here and granted summary judgment in favor of the Secretary.

Banks appealed to the Eleventh Circuit. However, that Court did not reach the collateral estoppel issue. As noted, the Secretary argued for the first time on appeal that Banks lacked Article III standing because, the Secretary said, Banks

suffered no injury in fact given that he was never required to pay for the TTFT treatments at issue. Rather, the manufacturer of device, Novocure, was found to be financially liable. Therefore, the Secretary said, Banks did not suffer the required injury that would confer Article III standing. Banks does not dispute that he received the treatments and was never required to pay for them out of his own pocket. However, as will be discussed in greater detail below, Banks disputed the Secretary's contention that he would be entitled to additional notice before he could ever be held personally liable for the cost of the TTF treatments. The Eleventh Circuit found this to be a factual dispute that was material to resolving the standing issue. Therefore, it remanded the case to this Court "for additional jurisdictional factfinding and a ruling on the issue of Article III standing in the first instance." *Banks v. Sec'y of Health & Hum. Servs.*, No. 21-11454, 2021 WL 3138562, at *1 (11th Cir. July 26, 2021). The Eleventh Circuit held that Banks should be allowed to develop a record on standing with "consideration of supplemental evidence submitted by the parties as appropriate." *Id.* at *4.

II. Medicare's Statutory Scheme

The statutes and regulations governing Medicare are legion. Thus, the Court will discuss only the portions of that scheme relevant to the issue at hand. In *Prosser v. Becerra*, 2 F.4th 708, 710–12 (7th Cir. 2021), a case with nearly identical facts, the Seventh Circuit succinctly described the relevant scheme. Like the appellant in

Prosser, Banks receives coverage from Medicare Part B, a supplementary medical insurance program administered by the Secretary through the Centers for Medicare and Medicaid Services, or CMS. Recipients pay a monthly premium in exchange for certain types of coverage, including for durable medical equipment like Novocure's Optune system. *See* 42 U.S.C. § 1395k. Part B does not cover services that “are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.” *Id.* § 1395y(a)(1)(A). The Secretary has interpreted “reasonable and necessary” to mean that an item or service must be safe and effective, medically necessary and appropriate, and not experimental in order to qualify for reimbursement. *See* Medicare Program Integrity Manual § 13.5.4.

CMS makes individual coverage decisions by determining whether a medical service is reasonable and necessary. While this determination often applies to each treatment decision, there are ways to extend coverage determinations to specific courses of treatment. These so-called local coverage determinations (“LCDs”) and national coverage determinations guide the individual claims decisions made by CMS.

When individuals first submit claims for coverage to Medicare Part B, they do so to local contractors who determine if the services or devices are covered or otherwise reimbursable under Medicare. *See* 42 C.F.R. § 405.920(a). Contractors

may issue an LCD that categorically decides whether a treatment is covered, a determination that becomes binding on the issuing contractor for future claims. *See* 42 U.S.C. § 1395ff(f)(2)(B).

A beneficiary disagreeing with the initial determination of coverage can appeal. Appeals proceed in four stages within the Medicare system. First, the beneficiary may request a redetermination from the Medicare contractor. *See* 42 U.S.C. § 1395ff(a)(3); 42 C.F.R. § 405.940. At the second level, the beneficiary may seek reconsideration by a qualified independent contractor. *See* 42 U.S.C. § 1395ff(b)(1)(A). A local coverage determination is not binding once a beneficiary reaches this stage of review. Claimants still unsatisfied with a coverage determination may proceed to step three by requesting a hearing through the Office of Medicare Hearings and Appeals, at which point the dispute is assigned to an ALJ for decision. *See* 42 U.S.C. § 1395ff(b)(1)(A), (d). A claimant may appeal an unfavorable decision by an ALJ to the Medicare Appeals Council (“MAC”), which represents the final decision of the Secretary. If the Council either affirms the coverage denial or does not render a decision within a 90-day timeframe, a beneficiary may bring a claim in federal district court. *See id.* § 1395ff(b)(1)(A) (incorporating 42 U.S.C. § 405(g)’s judicial review provisions).

Even when a benefits claim is denied at any level of the appeals process, the beneficiary is not necessarily stuck with the bill. If neither the supplier nor the

beneficiary knew or could reasonably have been expected to know that the claim would not be covered, Medicare will nevertheless pay for the service. *See id.* § 1395pp; 42 C.F.R. § 411.400(a). Banks and other plaintiffs around the country refer to this provision as a “Medicare Mulligan,” an apt term that the Court will use going forward. Beneficiaries get only one Medicare Mulligan—after that, both the beneficiary and supplier are presumed to be on notice that coverage is likely to be denied. In that way, § 1395pp provides suppliers and beneficiaries alike the benefit of the doubt and shields them both from financial liability the first time Medicare denies coverage.

But coverage denials are not always a risk-free proposition for a beneficiary. Suppliers may shift the risk of non-coverage solely to the beneficiary when they give advance written notice, often referred to as an Advance Beneficiary Notice (“ABN”), informing the beneficiary that Medicare is unlikely to cover the claim. *See* 42 C.F.R. § 411.404(a), (b). Medical device suppliers—as opposed to healthcare providers in general—bear an additional burden should they wish to shift the risk that coverage may be denied: they must obtain a written agreement by the patient that she will individually bear the cost of coverage denial. *See* 42 U.S.C. § 1395m(j)(4) (incorporating 42 U.S.C. § 1395m(a)(18)(A)(ii)); Medicare Claims Processing Manual ch. 30, § 30.1. In these ways, suppliers like Novocure are able to limit their financial risk while still providing innovative healthcare solutions like

TTFT. As will be discussed below, Banks argues that ALJ's denial of his claims caused him to lose his Medicare Mulligan and thus conferred Article III standing.

III. Article III Standing

Standing is a jurisdictional threshold to suit in federal court. *See Bochesse v. Town of Ponce Inlet*, 405 F.3d 964, 974 (11th Cir. 2005). “[O]nce a federal court determines that it is without subject matter jurisdiction, the court is powerless to continue.” *Univ. of S. Alabama v. Am. Tobacco Co.*, 168 F.3d 405, 410 (11th Cir. 1999). The lack of subject-matter jurisdiction defense is never waived. Fed. R. Civ. P. 12(h)(1). “If the court determines at any time that it lacks subject-matter jurisdiction, the court must dismiss the action.” Fed. R. Civ. P. 12(h)(3) (emphasis added). To establish standing, Banks must show that he has “(1) suffered an injury in fact, (2) that is fairly traceable to the challenged conduct of the defendant, and (3) that is likely to be redressed by a favorable judicial decision.” *Spokeo, Inc. v. Robins*, 578 U.S. 330, 338 (2016). Here, the Secretary claims that Banks suffered no injury in fact that is likely to be redressed by a favorable decision, i.e., that Banks cannot satisfy the first and third elements. (Doc. 65 at 12).

The Secretary presented this argument in a motion to dismiss pursuant to Fed. R. Civ. P. 12(b)(1). Banks responded to that motion and filed a brief of his own. There, he claims to have standing under three theories each of which, he says, demonstrate that he has suffered an injury in fact. First, Banks claims that he has

suffered an economic injury because he paid Medicare premiums and did not receive the promised benefits to which he was “entitled.” (Doc. 67 at 1). Second, Banks argues that he has suffered an injury from the denial of his statutory rights to have Medicare pay his claims. *Id.* Finally, Banks contends that he has suffered a present injury and/or suffers a substantial risk of future injury because he is or will be charged with knowledge of the denial of coverage in this case. That knowledge, Banks says, will cost him his entitlement to the Medicare Mulligan. Banks asserts that he will then be at risk of personal financial liability for future claims for TTFT coverage. The Court will address each of Banks’s contentions in turn.

A. Banks did not suffer an economic injury by paying his Medicare premiums and having his TTFT claims denied.

Banks first contends that he suffered an economic injury—which undoubtedly would constitute an injury in fact for standing purposes—when his claim for TTFT was denied despite the fact that he paid his Medicare premium for the relevant time period. At the hearing on this matter, Banks presented evidence that he paid \$1,608 in Medicare Part B premiums in 2018. (Doc. 82-1). After outlining his payment history, Banks laid out his economic harm as follows:

Assuming the allegations of the Complaint to be true (as the Court must at this stage), the Secretary failed to honor the promises of the statutes and improperly denied payment for qualifying items/services to which Mr. Banks was entitled. Thus, Mr. Banks is out of pocket at least the ~\$450-\$1,500 Mr. Banks paid for something he did not receive (i.e., Medicare coverage of qualifying claims).

(Doc. 67 at 4). The Court first notes that whether the claim at issue was improperly denied is not a factual allegation that must be presumed true for purposes of a motion to dismiss. It is a legal conclusion. Nevertheless, no Medicare beneficiary is entitled to have any and every claim approved and paid. What they are entitled to is the multi-tiered appeals process described above. There is no allegation that the Secretary denied Banks the ability to submit his claims and have the denials reviewed as provided for in the law.

Further, there is nothing in the record to suggest that Medicare denied every claim Banks submitted during the relevant period or that Medicare cancelled his coverage and kept the premiums. To suggest that Medicare, or any insurance company for that matter, is required to pay every claim that is submitted or else return the premiums makes little sense. The record before this Court demonstrates that Banks received everything to which he was entitled in exchange for his monthly premiums. Accordingly, the Court finds that he was not injured by paying \$1,608 in premiums in 2018.

B. Banks does not have standing based on the denial of his substantive statutory rights.

Banks next argues that he has standing based on the denial of his substantive statutory rights. Banks raised this argument on appeal. In its decision, the Eleventh Circuit noted that Banks “argues the violation of his statutory right to Medicare coverage alone is sufficient to establish standing.” *Banks*, 2021 WL 3138562, at *2

(11th Cir. July 26, 2021). However, the Court “ma[de] quick work” of that argument and held that it was “foreclosed by circuit precedent.” The Court held:

This Court has rejected the assertion that the allegation of a statutory violation alone is sufficient to confer standing. *See Muransky v. Godiva Chocolatier, Inc.*, 979 F.3d 917, 924 (11th Cir. 2020) (en banc) (“[W]e know one thing to be true—alleging a mere statutory violation is not enough to show injury in fact.”). Under *Muransky*, we instead must first ask if the statutory violation caused a direct harm to the plaintiff—if so, the plaintiff has stated an injury in fact. *Id.* at 926. In the absence of any direct harm, a plaintiff can still establish an injury in fact “by showing that a statutory violation created a ‘risk of real harm.’” *Id.* at 927 (quoting *Spokeo*, 136 S. Ct. at 1549). Banks’s argument that the statutory violation itself is sufficient to confer standing fails because it overlooks these requirements. Novocure, and not Banks, is liable for the cost of the January, March, and April 2018 claims. Because he does not have to pay these claims, Banks has not shown how the statutory violation caused a direct harm.

Id. at 3.

Banks acknowledges this in a footnote in his brief on standing:

Mr. Banks understands that, while not deciding the issue of standing, the Eleventh Circuit’s remand decision made certain comments regarding standing based solely on the denial of a statutory right. Respectfully, Mr. Banks believes that a more detailed review of the issue as contemplated by the Eleventh Circuit would either resolve the matter in Mr. Banks’ favor or properly present the issue for consideration by the Eleventh Circuit on appeal, if necessary.

(Doc. 67 at 7 n. 6). The Court finds the Eleventh Circuit’s opinion to be more than a comment on this issue. Rather, it held that the issue was foreclosed by circuit precedent. Accordingly, this Court declines to revisit that argument on remand.

C. Even if Banks lost his Medicare Mulligan, he does not have standing.

As described above, Medicare provides several layers of protection for its beneficiaries when it comes to personal financial liability for medical devices such as Optune. In situations where neither the beneficiary nor the supplier knew or reasonably should have known that a claim would be denied, Medicare will foot the bill on a one-time basis. According to Banks, the denial of his claims for the months of January, March, and April of 2018 serves to charge him with the requisite knowledge such that Medicare would not cover a subsequent denial under § 1395pp, i.e., the denial causes him to lose his Medicare Mulligan.

The Secretary contends that Banks has not lost his mulligan. According to the Secretary, Novocure would have to provide Banks with an ABN before he could be held financially liable for future TTF treatments. It is undisputed that Banks has not received such a notice.

Several district courts around the country have addressed nearly identical situations involving the denial of claims for TTFT to treat GBM and held that the beneficiaries lacked standing because any future financial risk is too attenuated from the denial of past coverage and far too speculative to establish standing. *See, e.g. Thumann v. Cochran*, No. 20-cv-125, 2021 WL 1222142 (S.D. Ohio Mar. 31, 2021)(finding that the plaintiff lacked standing and dismissing the case); *Wilmoth v. Azar*, No. 20-cv-120, 2021 WL 681118 (N.D. Miss. Feb. 22, 2021)(same); *Oxenberg v. Azar*, No. 20-cv-738 (E.D. Pa. Feb. 9, 2021)(same); *Komatsu v. Azar*,

No. 20-cv- 280, 2020 WL 5814116 (C.D. Cal. Sept. 24, 2020)(same); and *Pehoviack v. Azar*, No. 20-cv-661, 2020 WL 4810961(C.D. Cal. July 22, 2020)(same). The Court notes that at least one district court has found a beneficiary like Banks to have standing. *See Townsend v. Cochran*, 528 F. Supp. 3d 209, 218–19 (S.D.N.Y. 2021). However, that court found the plaintiff to have standing because he was “challenging the denial of Medicare benefits, i.e., a violation of a ‘substantive legal right conferred by statute....’” Because the Eleventh Circuit has held that argument to be foreclosed by circuit precedent, *Townsend* lends no support to Banks’s claim.

In each of the other cases, the district courts have found the plaintiff to lack standing. Like Banks, the plaintiffs in those cases had claims for TTFT denied, but were not required to pay out of pocket. Those plaintiffs also raised the Medicare Mulligan argument, but the courts found them to be meritless because of the attenuated chain of events necessary before personal financial liability could be imposed on the beneficiaries. Said another way, the threatened harm in those cases was not imminent.

For example, in *Wilmoth v. Azar*, No. 3:20-CV-120-NBB-RP, 2021 WL 681118, at *4 (N.D. Miss. Feb. 22, 2021), the district court found that the plaintiff did not know whether his future claims would be denied. The court noted that at least some of the plaintiff’s subsequent claims, like Banks’s, had been approved by Medicare. The court then noted that the applicable LCD was revised in September

of 2019 such that TTFT was covered in certain circumstances.¹ Therefore, the court held, “[a]n ALJ reviewing a future claim would have to ignore the revised LCD,” in order for denial to be a certainty. Additionally, the court held that the supplier, Novocure, would have to give the plaintiff an ABN that would shift payment obligations for future treatments to him before he would suffer an injury in fact. The court concluded that “[b]ecause Wilmoth's liability is dependent on not one, but a chain of decisions made by different actors, his alleged future harms are an ‘exercise in the conceivable’ but do not make a ‘factual showing of perceptible harm’ sufficient for Article III standing.” *Id.*

The Secretary argues that the same would be true in Banks’s case. However, Banks puts forth an argument that does not appear to have been raised in the other cases addressing this type of situation. According to Banks, it would not be necessary for Novocure to provide an ABN to him for him to be charged with the requisite knowledge to lose his Medicare Mulligan. The Secretary’s assertions aside, Banks has presented to this Court a decision from ALJ Leslie Holt in an unrelated case (“the Holt decision”) that he says belies the Secretary’s contention.² The Court hereby takes judicial notice of the Holt decision which appears as (Doc.

¹ Before that revision, the applicable LCD provided that TTFT was not reasonable and necessary and, therefore, was not covered under Medicare Part B. Neither the plaintiff in *Wilmoth* nor Banks have had claims evaluated under the revised LCD.

² Banks notes that ALJ decisions like this one are confidential. However, because Banks’s counsel happens to represent the subject beneficiary of the Holt decision, he was aware of this particular decision. Banks redacted all identifying information from the Holt decision.

72-1) on the docket sheet in this case. According to Banks, the ALJ in the Holt decision charged the beneficiary with knowledge of a past denial—and therefore deprived him of his Medicare Mulligan—even though that beneficiary was not given an ABN by the supplier. In his motion for discovery, Banks seeks production of all ALJ decisions that fall under particular parameters in order to find other decisions like ALJ Holt’s.

The Court first notes that it is not clear from the Holt decision whether that beneficiary received an ABN. The relevant portion of the Holt decision states that the record contains “an indication” that the beneficiary received written notice of non-coverage for TTFT. (Doc. 72-1 at 12). The decision goes on to say that the casefile contained “a letter written by the beneficiary appealing Medicare’s denial of his physician’s authorization request for coverage of TTF therapy using the Optune system.” *Id.* Therefore, the Holt decision held, it appeared “that as of [the date of the beneficiary’s letter], the Beneficiary was reasonably expected to know” that the Optune system was not covered. *Id.* Banks surmises that the beneficiary’s knowledge discussed in the Holt decision was based solely on a past denial of benefits. While it is clear that the beneficiary’s claim was denied, the decision says nothing about whether he received an ABN.

Further, the Holt decision was subsequently vacated by the MAC on procedural grounds. Specifically, the MAC found that the record was incomplete

and ordered the ALJ to “reconstruct the record or develop a new record and may take any action needed to dispose of this case.” (Doc. 69-3).³ Nothing in the record reveals the outcome of that case.

But even setting those concerns aside, there is a unique fact in Banks’s case. In his brief to this Court regarding standing, Banks stated: “Counsel understands from Mr. Banks that, against the advice of his doctors, Mr. Banks has elected to take a break from using the TTFT device but intends to resume use *if* his condition changes.” (Doc. 67 at 14, n. 10) (emphasis added). At the hearing on this matter, Banks’s counsel confirmed that Banks was not presently using the device but planned to resume using it if his condition changed. According to counsel, Banks stopped using the device because of an allergic reaction to the adhesive that affixed the device to his head. The Court sympathizes with and understands Banks’s decision. However, that decision undermines his standing argument.

Before this Court and the Eleventh Circuit, Banks took the position that he was all but certain to submit claims for TTFT in the future. *See Banks*, 2021 WL 3138562, at *3 n. 2 (11th Cir. July 26, 2021)(“Banks says he is all but certain to submit additional claims for TTFT coverage in light of his present and consistent reliance on the device to treat his glioblastoma multiforme. *See Appellant’s Br.* at 2 (Banks has used the TTFT device since 2013 and believes his ‘medical need for

³ The Court also takes judicial notice of this decision.

TTFT treatment has been the same.’); R. Doc. 1 ¶ 17 (‘[P]atients prescribed TTFT treatment will have to continue that treatment for the rest of their . . . lives.’’’)). However, that position has now changed; it is no longer clear when or if Banks will resume using the Optune system and submit a new claim.

Even assuming that the Holt decision stood for Banks’s proffered proposition and that discovery would uncover similar cases, the fact that Banks is not currently using the device (and has only speculative offerings regarding future use) diminishes any imminence that would have otherwise been present. Even if Novocure does not have to provide Banks an ABN, a point the Secretary disputes, the chain of events leading to a future possibility of financial liability is too attenuated to confer standing. First, and most importantly, Banks would have to decide to start using the device again. There is no way for the Court to say whether and when that will be. Second, he would have to submit a new claim that would be reviewed under the revised LCD.⁴ Then, if the claim is denied, it would have to be denied at all other levels of the Medicare appeals process. Only then would Banks suffer any concrete injury sufficient to confer Article III standing. Accordingly, the Court finds that Banks has failed to establish that he suffered an injury in fact, a necessary element to confer standing. *See Spokeo*, 578 U.S. at 338. Because the Court finds that Banks

⁴ At oral argument, Banks asserted that his particular medical situation makes it likely that his claim would be denied under the revised LCD. However, the Court finds that assertion to be too speculative to confer standing.

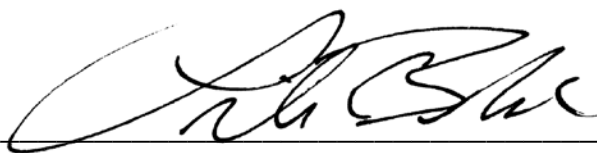
has failed to establish the first prong of the standing analysis, it is not necessary to discuss the Secretary's contention as to the redressability prong.

IV. Conclusion

Like the similarly situated plaintiffs in the cases cited above, Banks has suffered no injury in fact and any threat of future injury is too attenuated to confer Article III standing, i.e. the future threat is not imminent. This is particularly true in Banks's case given his decision to take a break from using the device in question. Accordingly, the Court **GRANTS** the Secretary's motion to dismiss (Doc. 65), and this case is **DISMISSED WITHOUT PREJUDICE**. Further, the Court finds that the discovery Banks seeks would not change the outcome of this case. As noted above, even if he found cases supporting his position, the fact that he is not presently using the device renders his standing argument meritless. Therefore, Banks's motion for discovery (Doc. 66) is **DENIED**.

The Clerk is directed to close this case.

DONE and **ORDERED** December 16, 2021.



LILES C. BURKE
UNITED STATES DISTRICT JUDGE

